UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,416	11/28/2000	Hong Jin	7682-052-999	7604

20583 7590 02/07/2006

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
LUCAS, ZACHARIAH	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,416	JIN ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49,51-53,55-58,60-63 and 65-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49,51-53,55-58,60-63 and 65-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-6-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 49, 51-53, 55-58, 60-63, and 65-83 are pending and under consideration in the application.

2. In the prior action on the merits, mailed on October 6, 2004, claims 49, and 51-70 were pending, with claims 49, and 51-69 rejected, and claim 70 objected to. In the Response filed on April 6, 2005, claims 49, 57, 58, and 70 were amended, claims 54, 59, and 64 were cancelled; and claims 71-83 were added to the application.

A new Requirement for Restriction was mailed on August 10, 2005 in view of the newly added claims (esp. claim 72). In the response of November 10, 2005, the Applicant elected with traverse Group I of the election requirement- drawn to recombinant viruses comprising a modified M2-2 ORF.

3. Applicant's election with traverse of Group I in the reply filed on November 10, 2005 is acknowledged. The traversal is on the ground(s) that there would be no undue burden in the examination of each of the claimed inventions. The Applicant asserts that the common classification demonstrates that the four inventions may be examined together. This is not found persuasive because a separate search would be required for each of the claimed inventions. The fact that the different inventions do not have different classifications is not evidence that there would be no undue burden. For example, there are many different types of viruses, attenuated forms of which would all also fall within the same classification as the present inventions. However, it would be readily apparent that a search for any one of such other attenuated viruses would require a different search from the presently claimed inventions. Thus, the common

classification does not demonstrate that there is additional burden in examining the different inventions in the current application.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on April 6, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Objections

5. **(Prior Objection-Withdrawn)** Claim 70 was objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependant on another multiple dependant claim. In view of the amendment of the claim, the objection is withdrawn.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. **(New Rejection)** Claims 49, 51-53, 55-57, 60-63, 69, 71-73, 75, 77, 78, 83 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are rejected based on the doctrine of claim differentiation. Claims 57, 60-63, 69, 71-73, 75, 77, 78, 83 read on substantially identical subject matter to claims 58, 65-72, 74, and

79-83, except that the latter set of claims require that the genomic modification is "not found in the genome of a native RSV." Because this language is the only difference between the rejected claims and the other cited claims, the rejected claims must be read to include embodiments wherein the genomic modification in the claimed viruses represent modifications that are found in native RSV, and therefore represent viruses that are found in nature. The claims are therefore rejected as reading on products of nature.

Further, because claims 49, 51-53, 55, and 56 do not include the claim language "not found in the genome of a native RSV," and are therefore read to be consistent with the language of claims 57, 60-63, 69, 71-73, 75, 77, 78, 83. The rejection is therefore also applied against these claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **(New Rejection- Necessitated by Amendment)** Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim purports to depend from claim 732. However, there is not such claim present in the claim listing. It is therefore unclear what is being further limited, and therefore what is being claimed.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Restated and Maintained)** Claims 49-53 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for anti-RSV vaccines. For the reasons indicated below, the rejection is extended to claims 55 and 56, which were inadvertently left out of the prior statement of the rejection. The rejection is also extended to new or amended claims 70, 71, and 73-83. It is noted that, although claim 73-83 are not specifically drawn to vaccines, they are drawn to "pharmaceutical compositions" comprising the same attenuated viruses. By claiming such pharmaceutical compositions, the claims are indicating that the compositions have a therapeutic effect- which would include anti-RSV vaccines, or the use of attenuated viruses sufficiently attenuated to safely act as a carrier for another encoded heterologous protein.

In Response, the Applicant has submitted arguments, and information in support thereof, indicating that those in the art have successfully developed certain recombinant attenuated RSV viruses as vaccines. These arguments are persuasive in part. However, while the art indicates that RSV vaccines in general may be enabled, there is not sufficient evidence to demonstrate that the Applicant is enabled for the use of any of the claimed viruses as anti-RSV vaccines. As the Applicant notes on page 10 of the Response, there must be a reasonable correlation between the scope of enablement provided in the specification and that which is claimed.

The claims in the present application are drawn to any RSV vaccines wherein virus comprises a genetic modification. The claims indicate that the modification may be any insertion or deletion to the viral genome, or any insertion, deletion, or substitution of a complete open

reading frame of the genome. As the Applicant has described, the references in the art indicate that specific modifications to the viral genome do result in viruses sufficiently attenuated, but also sufficiently immunogenic, to provide for a protective response in animal models. However, the teachings of these references are also limited to specific modifications. Moreover, the modifications of such references relate to genetic modifications not within the scope of the current claims (the temperature sensitive variants of that reference are the result of substitutions, not insertions or deletions, in the genomic sequence). The teachings of the art also indicate that not every modification results in a virus with such a balance between attenuation and immunogenicity. See e.g., the teachings of Tang and Prince (referred to on page 7 of the February 2004 action- which teach that despite a large number of candidate vaccines none had been identified as safe and effective). As has previously been described, the art indicates that there is significant complexity and unpredictability in the making of such attenuated viruses.

While the art indicates that recombinant techniques, such as those described in the present application, permit the construction and evaluation of a broad range of mutations (see e.g., Crowe et al., Vaccine 20(supp 1): S32-37; and Wright, J Infect Dis 182: 1331-42, at 1341), this does not overcome the inherent unpredictability in determining what modifications would result in viruses comprising sufficient attenuation. Moreover, the Applicant's own teachings indicate that many modifications either have no effect on or increase the operability of viral genes (thus resulting in a virus with no attenuation, or that is more virulent, compared to the wild-type infectious virus), or result in non-viable viruses- neither of which outcomes results in a virus useful as a vaccine. See e.g., App., pages 60-63. Thus, even if the art indicates that the Applicant may be enabled for the use of specific attenuated viruses comprising specific

attenuating mutations as anti-RSV vaccines, neither the art nor the present application demonstrates that mere ability to produce viral attenuations automatically enables those in the art to produce any anti-RSV vaccine without undue experimentation. The methods described merely permit those in the art to run the numerous trials required to identify such viruses.

In addition, the present application provides little guidance as to full scope of modifications that may be made. While the application does disclose certain modifications to the L protein, and describes rescued virus comprising deletions of certain genes, there is no demonstration that the disclosed viruses result in sufficiently attenuated viruses for use as vaccines. Further, the modifications disclosed with respect to the L protein fall outside the scope of the present claims as they identify substitutions, and not insertions or deletions. While the application also suggests other regions in the RSV genome where attenuating mutations may be attempted, there is no identification of specific positions or modifications that would result in an attenuated phenotype. Thus, the claims are drawn to a broad genus of attenuated viruses, the scope of which those in the art would be required to identify for themselves.

In view of the breadth of the claims, the unpredictability in the art, and amount of experimentation that would be required to practice the full scope of the claims, and the comparatively limited guidance presented, the application is not found enabling for any vaccine according to the rejected claims for the reasons above, and for the reasons of record. Thus, while the Applicant's arguments are found persuasive in part, they are not deemed sufficient to demonstrate that the application has provided sufficient enabling support to reasonable correlate to the scope of what is claimed.

12. **(Prior Rejection- Maintained)** Claims 49, and 51-69 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The rejection is withdrawn from claims 50, 54, 59, and 64, which have been cancelled from the application. However, the rejection is extended to new (or amended) claims 70-83. The claims read on genetically manipulated (recombinant) attenuated infectious RSV comprising any insertion or deletion, or any insertion, substitution, or deletion of an entire open reading frame (ORF).

The Applicant traverses this rejection on the basis of their assertion that they have provided an enabling disclosure, and that the experimentation required to identify the claims viruses in the present application is not undue. In particular, the Applicant asserts that there is no requirement for a "reasonable certainty before performing" an experiment that it will succeed so long as there is a reasonable amount of guidance with respect to the direction of the experimentation.

As previously indicated, the Wands case put forth a series of factors to be considered in making a determination as to whether an application is enabling for a claimed invention. The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Applicant asserts that the Wand decision indicates that there is no requirement for a reasonable certainty that the experiment would be successful a priori, so long as a reasonable amount of guidance has been presented. The Applicant then continues on the assert that the application

teaches methods for the modification and screening of modified virus, and provides adequate guidance with respect to the direction of experimentation.

The Wands case related to the production of antibodies against a particular antigen that were able to bind to the antigen with high affinity. The court determined that the Applicant was enabled for methods of using such antibodies as the application disclosed a method for the production of such antibodies, in combination with a number of working examples. It is noted that the court characterized the experiment for identifying the antibodies as the entire process of immunizing an animal, forming hybridomas, and screening the hybridomas for antibodies with the required affinity. 8 U.S.P.Q. 2d, at 1407. The court also noted that "Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations." Id. Based on this characterization, the court determined that the teachings of the application enabled the scope of the claimed invention- methods of using any antibody with the indicated level of affinity for the identified antigen. Thus, the Wands case involved a situation in which a single experiment with no variable factors was repeated, and where an operable embodiment resulted in each instance.

In the present case, the claims are broadly drawn to any recombinant attenutated RSV comprising any insertion or deletion. The application provides several suggestions as to the types and placement of modifications that may be made to the viral genomes, and provides examples of experiments that resulted in both operational and in non-functional viruses. See e.g., pages 58-59. Unlike the experimentation involved in the Wands case, each experiment in the present instance involves the production of a single specific viral mutant, and the testing of this specific mutant to determine if it is indeed replication competent and infectious. If one looks to RSV

alone, with a genome of over 15,000 nucleotide bases, this permits a large number of potential insertions and deletions, each of which represents a different variable and experiment to be performed.

The Applicant asserts that they have provided guidance as to where to make the modifications. In particular, the Response notes several suggestions as to the types of modifications that may be made. For example, the application indicates that certain regulatory regions can be modified to obtain attenuated viruses, and that modifications can be introduced into the viral surface antigens to interfere with the binding affinity of the virus to the host cell. App., page 23-25. However, while the application provides such general suggestions, the is comparatively little guidance (given the size of the viral genome) as to what specific modifications can be made to each of the various RSV sequences that would result in the claimed viruses. Additionally, while the present application provides examples of specific substitutions (point or of entire ORFs) that may result in attenuated RSV, the application does not provide many, if any, examples of individual insertions or deletions that may be made to the viral genome to arrive at an attenuated phenotype. Thus, there is no specific guidance to those in the art as to what additions and deletions may be made to the RSV genome to produce the claimed compositions.

Such specific guidance is, however, required as was demonstrated on pages 60-63. This portion of the specification illustrates that different modifications to the same region of the viral genome can have very different effects- resulting unpredictably in both viruses within or outside of the claimed genus. Thus, the present case is drawn to a broad genus in an uncertain art, and for which comparatively few working examples have been provided. Further, those working

examples which have been provided provide little information as to the operability of modifications outside of the L gene, or even to the operability of other modifications within this gene. Further, unlike the Wands case which involved relatively little experimentation in that the exact same process was repeatedly performed, the practice of the full scope of the invention in the present case requires that those in the art perform repeated experiments with numerous variables (the different potential modifications) with little guidance as to the specific modifications that would result in virus according to the claims.

The Applicant further asserts that the *Angstadt* case supports their conclusion that the application provides enabling support for the claimed genus. In particular, the Applicant asserts that the decision held the claims at issue therein enabled on the grounds that the skilled artisan would have read the inventor's specification for directions in making the compounds at issue, and would then determine if such compounds had been made. However, this is not the sole basis on which the Court found enablement in that case. The *Angstadt* court repeatedly referred to the forty successful experiments of the inventor in that case, also noting that only one of the tested compounds was not effective. 190 U.S.P.Q. 214, at 218. Further, the court also noted that the experiments required to test the various substances were not complex or complicated. Thus, unlike the present case which does involve complex manipulation of genes, in which a large number of inoperative embodiments have been shown, and for which there is little predictability with reference to other potential manipulations, and for the reasons indicated in the prior action, the Applicant reliance on *Angstadt* does not appear well founded.

The same factors relating to the present case indicate that, given the scope of the present claims, the application has not provided sufficient guidance to enable those in the art to make or

use viruses according to the rejected claims without undue experimentation. In the present case, as demonstrated on pages 60-63, each time the experiment is performed, there is no indication that the tested virus will be viable and attenuated. If the application had provided some teachings that would enable those in the art to easily determine which mutations are likely to result in such lethality, or more preferably, which would result in an attenuated phenotype, the Applicant's arguments would be more persuasive. However, the teachings in the application provide no such means other than making each of the potential viruses and discovering for themselves which mutations lead to what effects.

For these reasons and the reasons of record, the rejection is maintained.

13. **(New Rejection)** Claims 49, 51-53, 55-58, 60-63, 65-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims read on vaccines, pharmaceutical compositions, or immunogenic compositions comprising a recombinant attenuated RSV the genome of which has been modified with an addition, deletion, or a substitution of an entire ORF. Dependent claims further specify a region where the modification is made, or further require that the virus is capable of only a single round of replication.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions, the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

Additionally, recent cases also identify other factors that may be considered in making a determination as to whether a claimed invention is adequately supported by the application's description. Such factors may include the predictability in the art. See e.g., *Capon v. Eshhar*, 76 U.S.P.Q.2d 1078 (CAFC 2005), at 1085. Further, the courts have also indicated that, with reference to written description, distinction must be made 'among generic inventions that are adequately supported, those that are merely a "wish" or "plan,"... and those in between.' Id., at 1086. Further, the courts have also indicated that the disclosure of a method for the identification of a compound or group of compounds is not a description of the compound(s) identified thereby. See e.g., MPEP § 2163(A)(3)(a), and *University of Rochester v. G.D. Searles & Co.*, 69 U.S.P.Q. 2d 1886, at 1894-95 (CAFC 2004). Based on such considerations with respect to the description provided in the present application, there is insufficient support for the full scope of the inventions claimed.

The present claims identify three functional aspects of the claimed compositions (immunogenicity is considered inherent to the virus). All of the claimed viruses are required to be attenuated in nature. A subset of these are also required to be capable of inducing a protective or therapeutic immunogenic anti-RSV response. Another subset is required to be capable of only a single round of replication. The claims also require that the claimed viruses meet the structural requirements of comprising at least one addition or deletion, or comprising a substitution of a complete viral ORF. However, the claims permit these modifications to be anywhere in the RSV genome, which comprises over 15,000 nucleotide bases. Thus, the claims cover a genus comprising a vast number of potential viruses identified only by their function and a general description of the required structure.

The application also provides examples of certain modifications (albeit- no specific additions or deletions) that may result in attenuated viruses, and suggests other general locations in the viral genome where modifications having the desired results may be found. However, as was indicated above, the examples in the application teach that different modifications, even of nucleotides not spaced far apart in the viral genome, result in viruses with different phenotypes. These teachings indicate that the various functional requirements of the claimed viruses do not correlate with the presence of additions, deletions, or substitutions in general, but rather are specific to particular modifications at particular sites within the viral genome. Further, these described results also indicate that the effect of any particular modification is largely uncertain. Both of these indications correspond to teachings in the art, such as in the Bowie reference previously described (see e.g., page 11 of the October 2004 action), which teach that the effects of any particular modification to a base or residue in a biological sequence is largely dependent

on the relationship of the modified base or residue to the function and structure of the sequence as a whole.

In view of this uncertainty, and the lack of any identification of any general structure or modification to the desired functions, the application has not provided sufficient written description support for the claimed genus. While certain species may have been disclosed, the uncertainty in the art indicates that further teachings would be required to demonstrate possession of the entirety of the claimed genus. As drawn to the species not specifically disclosed, the claims represent a genus of inventions for which the application has a plan to determine, but which remain unknown at present. This is highlighted by the reliance of the application on the disclosed methods for screening for viruses with the required functions for descriptive support. See e.g., App., pages 6 (referring to the selection of virus variants with the desired traits) and 28 (relating a screening method for the selection of the desired variants). However, as indicated above, description of a method for identification of a compound is not the same as describing the compound itself.

In the instant case, given that the disclosed species provide little information as to the identity of non-disclosed species, the uncertainty in the art, the lack of any demonstration that the identified functions correlate to the present of the required structural features, and the lack of any other non-functional means for the identification of members of the claimed genus, the present application does not provide adequate support for the scope of the genus claimed.

Claim Rejections - 35 USC § 102

14. **(Prior Rejections- Withdrawn)** Claims 49, 52, 54, 57, 58, 59, 63, 64, and 68 were rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al., Infection and Immunity 37: 397-400. Claims 49, 51, 52, 54, 57, 58, 59, 62, 63, 64, 67, and 68 were rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al., Journal of Pediatrics (of record in the IDS of March 2001). Claims 49, 51, 52, 54, 57, 58, 59, 62, 63, 64, 67, and 68 were rejected under 35 U.S.C. 102(b) as being anticipated by Crowe et al., Vaccine 11(14): 1395-404. The viruses described in each of these references relate to viruses comprising single point mutations (i.e. substitutions) induced by a chemical mutagen. The claims have been amended to require that the claimed viruses comprise a nucleotide addition, deletion, or to comprise a substitution of an entire open reading frame. These amendments exclude embodiments such as are disclosed by the cited references. The rejections are therefore withdrawn.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. **(New Rejection- Necessitated by Amendment)** Claim 72 is rejected under 35 U.S.C. 103(a) as being obvious over Murphy et al., U.S. Patent 5,993,824 (of record in the action mailed on June 5, 2002). This claim reads on a composition comprising a virus comprising an addition, deletion, or substitution of an entire ORF, wherein the modification is to the M2-2 ORF. While the Applicant has support for the insertion, deletion, or substitution of the M2-2

ORF of RSV in the parent application 09/161,122, there does not appear to be support for the embodiment of claim 21 in application 08/316,439 (now U.S. Patent 5,840,520). Nor does the 08/316,439 application appear to provide support for any substitution or deletion of any RSV ORF. Thus, the Applicant is not accorded priority of the indicated claims to the 08/316,439 application.

The Murphy patent teaches that the genes for target proteins of RSV may be substituted or deleted in the recombinant virus made according to the disclosure. See e.g., columns 5-6. Additionally, the reference indicates that the M2-2 protein is not required for viral replication, and actually hinders replication of the virus. See e.g., columns 84-85. It would therefore have been obvious to those in the art to produce RSV comprising a deletion of the M2-2 gene so as to provide for the necessity of the M2-1 gene, but to avoid the loss of replication due to inclusion of M2-2 inhibitory activity. The teachings of the indicated reference therefore render the claimed invention obvious.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. **(New Rejection)** Claims 49, 51-53, 55-58, 60-63, 65-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7, 10, 12, 21, and 22 of copending Application No. 09/724,388. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are generic to the present applications. Further, the specification of the copending application contains all of the teachings of the present application, and identifies the additional limitations of the dependent claims in the present application as falling within the scope of the claimed inventions in the copending application. See e.g., pages 20-24 of the copending application. Thus, the present claims represent obvious variations to the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. **(New Rejection)** Claims 49, 51-53, 55-58, 60-63, 65-83 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-31, 34, and 36 of copending Application No. 10/876,113. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application claim overlapping subject matter to the present applications. The claims of the copending application read on subject matter that overlaps in scope to the present claims. The

difference between the present claims and those of the copending application are that the copending application also reads on embodiments wherein the RSV is specifically stated to include a sequence heterologous to the RSV genome. Thus, the copending claims overlap with, and are obvious over the present claims.

20. **(New Rejection)** Claims 49, 52, 55-58, 60, 61, 63, 65, 6, 68, 70, 72, 73-76, 78-80, and 82 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2, 17, 18, 23, and 35 of copending Application No. 10/975,060. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims read on a species of the presently claimed invention and suggested by present claim 72.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. **(New Rejection)** Claims 49, 52, 55-58, 60, 61, 63, 65, 6, 68, 70, 72, 73-76, 78-80, and 82 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/078-900. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims read on a species of the presently claimed invention and suggested by present claim 72.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

22. **(New Rejection)** Claims 49, 52, 55, 57, 58, 60, 63, 65, 68, 71, 73-75, 78, 79, and 82 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6and 7 of U.S. Patent No. 5,840,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are read on overlapping subject matter with the issued claims. Claims 6 and 7 read on chimeric RSV comprising a heterologous sequence. The patent specification teaches the insertion of the heterologous sequence into a functional (protein coding) domain so as to result in an attenuated chimeric virus. Column 47, lines 49-59. The present claims read on an attenuated RSV comprising an addition to the nucleotide sequence. Thus, the present claims read on the disclosed embodiment of the patent claims. The present claims are therefore rejected for double patenting as being anticipated by obvious species embodied by the patent claims.

23. The above rejections are, in part, based on the specification of a previously issued patent, rather than the claims. In support of the use of this material, the examiner notes the following excerpt from MPEP section 804 II(B)(1):

> When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure.
>
> The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court pointed out that "this use

> of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined."

Thus, the courts have held that it is permissible to use the specification in determining what is included in, and obvious from, the invention defined by the claim on which the rejection is based. This is true even where elements are drawn from the specification describing the claimed invention which are not elements in the claim itself.

Conclusion

24. No claims are allowed.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 2/6/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600